S.I. No 398 of 1999

European Communities (Additives in Feedingstuffs) Regulations, 1999

I, Joe Walsh, Minister for Agriculture, Food and Rural Development, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No 27 of 1972), and for the purposes of giving effect to Council Directive 96/51/EC of 23 July 1996[1], Council Directive 98/92/EC of 14 December 1998[2], Council Decision 98/728/EC of 14 December 1998[3], Council Directive 99/20/EC of 22 March 1999[4] and for the purposes of giving effect to Council Directive 70/524/EEC of 23 November 1970[5] as amended by Council Directive No 73/103/EEC of 28 April 1973[6], Council Directive No 75/296/EEC of 28 April 1975[7], Council Directive No 84/587/EEC of 29 November 1984[8], Commission Directive No. 91/248/EEC of 12 April 1991[9], Commission Directive No. 91/249/EEC of 19 April 1991[10], Commission Directive No. 91/336/EEC of 10 June 1991[11], Commission Directive No. 91/508/EEC of 9 September 1991[12],Commission Directive No. 91/620/EEC of 22 November 1991[13], Commission Directive No. 92/64/EEC of 13 July 1992[14], Commission Directive No. 92/99/EEC of 17 November 1992[15], Commission Directive No. 92/113/EEC of 16 December 1992[16], Commission Directive No. 93/27/EEC of 4 June 1993[17], Commission Directive No. 93/55/EEC of 25 June 1993[18], Commission Directive No. 93/107/EEC of 26 November June 1993[19], Council Directive No. 93/114/EC of 14 December 1993[20], Commission Directive No. 94/17/EC of 22 April 1994[21], Commission Directive No. 94/40/EC of 22 July 1994[22], Commission Directive No. 94/41/EC of 18 July 1994[23], Commission Directive No. 94/50/EC of 31 October 1994[24], Commission Directive No. 94/77/EC of 20 December 1994[25], Commission Directive No. 95/37/EC of 18 July 1995[26], Commission Directive No. 95/55/EC of 31 October 1995[27], Commission Directive No.

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[1] O.J. No L 235, 17.9.96, p 39
[2] O.J. No L 346, 22.12.98, p 49
[3] O.J. No L 346, 22.12.98, p 51
[4] O.J. No L 80, 25.3.99, p. 20
[5] O.J. No L 270, 14.12.70, p. 1
[6] O.J. No L 124, 10.5.73, p 17
[7] O.J. No L 124, 15.5.75, p29
[8] O.J. No L 319, 8.12.84, p13
[9] O.J. No L 124, 18.5.91, p1
[10] O.J. No L 124, 18.5.91, p43
[11] O.J. No L 185, 11.7.91, p31
[12] O.J. No L 271, 27.9.91, p67
[13] O.J. No L 334, 5.12.91, p62
[14] O.J. No L 221, 6.8.92, p51
[15] O.J. No L 350, 1.12.92, p83
[16] O.J. No L 16, 25.1.93, p2
[17] O.J. No L 179, 22.7.93, p5
[18] O.J. No L 206, 18.8.93, p11
[19] O.J. No L 299, 4.12.93, p44
[20] O.J. No L 334, 31.12.93, p24
[21] O.J. No L 105, 26.4.94, p19
[22] O.J. No L 208, 11.8.94, p15
[23] O.J. No L 209, 12.8.94, p18
[24] O.J. No L 297, 18.11.94, p27
[25] O.J. No L 350, 31.12.94, p113
[26] O.J. No L 172, 22.7.95, p21
[27] O.J. No L 263, 4.11.95, p18

96/7/EC of 21 February 1996[28], Commission Directive No. 96/66/EC of 14 October 1996[29], Commission Directive No. 97/6/EC of 30 January 1996[30], Commission Directive No. 97/72/EC of 15 December 1997[31], Commission Directive No. 98/19/EC of 18 March 1998[32],hereby make the following Regulations:

Part I
Preliminary

1. These Regulations may be cited as the European Communities (Additives In Feedingstuffs) Regulations, 1999.

2. (1) In these Regulations -

"approved establishment" means an establishment granted approval in accordance with Article 2(2) of Council Directive 95/69/EC of 22 December 1995[33],

"approved intermediary" means an intermediary granted approval in accordance with Article 3(1) of Council Directive 95/69/EC of 22 December 1995[33],

"authorised officer" means a person appointed by the Minister under Regulation 25 to be an authorised officer for the purposes of these Regulations;

"authorization" means authorization in accordance with the Council Directive;

"authorised additive" means an additive which has been granted a Community authorization;

"community authorization" shall be construed in accordance with Article 3 of the Council Directive;

"the Council Directive" means Council Directive 70/524/EEC of 23 November , 1970[5] as amended by Council Directive No 73/103/EEC of 28 April 1973[6], Council Directive No 75/296/EEC of 28 April 1975[7], Council Directive No 84/587/EEC of 29 November 1984[8], Commission Directive No. 91/248/EEC of 12 April 1991[9], Commission Directive No. 91/249/EEC of

[28] O.J. No L 51, 1.3.96, p45
[29] O.J. No L 272, 25.10.96, p32
[30] O.J. No L 35, 5.2.97, p11
[31] O.J. No L 351, 23.12.97, p55
[32] O.J. No L 96, 28.3.98, p39
[33] O.J. No L332, 30.12.95, p15

19 April 1991[10], Commission Directive No. 91/336/EEC of 10 June 1991[11], Commission Directive No. 91/508/EEC of 9 September 1991[12], Commission Directive No. 91/620/EEC of 22 November 1991[13], Commission Directive No. 92/64/EEC of 13 July 1992[14], Commission Directive No. 92/99/EEC of 17 November 1992[15], Commission Directive No. 92/113/EEC of 16 December 1992[16], Commission Directive No. 93/27/EEC of 4 June 1993[17], Commission Directive No. 93/55/EEC of 25 June 1993[18], Commission Directive No. 93/107/EEC of 26 November 1993[19], Council Directive No. 93/114/EC of 14 December 1993[20], Commission Directive No. 94/17/EC of 22 April 1994[21], Commission Directive No. 94/40/EC of 22 July 1994[22], Commission Directive No. 94/41/EC of 18 July 1994[23], Commission Directive No. 94/50/EC of 31 October 1994[24],Commission Directive No. 94/77/EC of 20 December 1994[25], Commission Directive No. 95/37/EC of 18 July 1995[26], Commission Directive No. 95/55/EC of 31 October 1995[27], Council Directive 95/69/EC of 22 December, 1995[33], Commission Directive No. 96/7/EC of 21 February 1996[28], Council Directive 96/25/EC of 29 April, 1996[37] , Council Directive 96/51/EC of 23 July, 1996[1], Commission Directive No. 96/66/EC of 14 October 1996[29], Commission Directive No. 97/6/EC of 30 January 1996[30], Commission Directive No. 97/72/EC of 15 December 1997[31], Commission Directive No. 98/19/EC of 18 March 1998[32];

"Directive 95/69/EC" means Council Directive No 95/69/EC of 22 December 1995[33];

"the Minister" means the Minister for Agriculture, Food and Rural Development;

"official methods of analysis" means a method of analysis specified in the European Communities (Feedingstuffs) (Methods of Sampling and Analysis) Regulations, 1999 (S.I. 289 of 1999);

"registered establishment" means an establishment registered in accordance with Article 7(2) of Directive 95/69/EC;

"State Chemist" means the head of the State laboratory or a person authorised in writing by him or her to perform the functions assigned to the State Chemist under these Regulations.

(2) A word or expression that is used in these Regulations and is also used in the Council Directive shall, unless the contrary intention appears, have in these Regulations the same meaning that it has in the Council Directive.

(3) In these Regulations, unless otherwise indicated -

(a) a reference to a Regulation is a reference to a Regulation of these Regulations, and

(b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs.

3. (1) Subject to this Regulation, these Regulations shall apply to additives in feedingstuffs.

(2) These Regulations shall not apply to processing aids used deliberately as substances in the processing of feed materials or of feedingstuffs in order to achieve

[37] O.J. No L125, 23.5.96, p. 35

a certain technological objective during treatment or processing which may result in the unintentional but technically unavoidable presence of residues of the substances or their derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

(3) Provided they are not derived from products specially enriched with substances corresponding to additives, substances present in their natural state in feed materials which are part of the normal composition of feedingstuffs and which correspond to a substance authorized under these Regulations shall not be regarded as additives.

(4) The Minister may authorise, but only for practical tests conducted for scientific purposes and for non-commercial ends, the use as additives of products which are not authorised at Community level or the use of additives under conditions other than those laid down in the authorization regulation, provided that:

(a) the tests are carried out in accordance with the principles and conditions laid down in Directive 87/153/EEC[34], and

(b) an adequate official inspection has been performed.

(5) These Regulation shall not apply to additives, premixtures and feedingstuffs which are shown by appropriate indications to be exclusively for export to countries which are not Member States of the European Union.

4. (1) Where the Minister acts as rapporteur for the examination of dossiers arising from the obligations laid down in Articles 4(2), 9b(1), 9c(3) and 9g(4) of the Council Directive, a fee to be determined by the Minister may be charged on application according to the additive group and the nature of the Community authorization requested. The fee shall be payable to the Minister at the time of submission of the dossiers for such examination.

Part II
Additives, Premixtures and Feedingstuffs

5. (1) A person shall not put into circulation an additive, or a premixture or feedingstuff containing an additive, unless -

(a) a Community authorization has been granted for the additive;

(b) the additive complies with the conditions, if any, specified in the said authorization.

(2) A person shall not incorporate an additive in a premixture or feedingstuff unless -

(a) a Community authorization has been granted for the additive

(b) the additive is incorporated in the premixture or feedingstuff in accordance with the conditions, if any, specified in the said authorization.

[34] O.J. No L 64, 7.3.87, p.19

(3) Subject to paragraph (4), a person shall not use an additive for the purposes of animal feeding unless:-

(a) a Community authorization has been granted for the additive;

(b) the additive has been incorporated in a feedingstuff in accordance with the conditions, if any, specified in the said authorization;

(4) Additives belonging to groups other than antibiotics, coccidiostats and other medicinal substances, and growth promoters may be used if administered by a method other than incorporation in feedingstuffs, on condition that the method is provided for in the Community authorization.

(5) A person shall not have on any premises an additive, or a premixture or feedingstuff in which an additive has been incorporated, unless a Community authorization has been granted for the additive and the specifications and use of the additive, premixture or feedingstuff complies with the requirements laid down in the Community authorization.

6. The person responsible for putting the additives referred to in Annex A, Part A to the Council Directive into circulation shall, upon request, make available to the Minister a standard sample having the characteristics and properties described in the monograph referred to in Article 9p of the Council Directive, together with a reference sample of the active substance. If the characteristics or properties of the additives are modified, a new standard sample corresponding to the new monograph must be provided.

7. (1)Subject to paragraph (2), a person shall not mix additives in premixtures or feedingstuffs unless, in relation to the effects desired, there is physio-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

(2) A person shall not mix-

(a) antibiotics and growth promoters together, either with substances from their own group or with substances from the other group,

(b) any coccidiostats and other medicinal substance with antibiotics and growth promoters where such coccidiostats also act, for the same category of animal, as an antibiotic or a growth promoter, or

(c) coccidiostats and other medicinal substances if their effects are similar,

unless the mixture concerned is the subject of a specific Community authorization as an additive.

(3) A person shall not mix antibiotics, growth promoters, coccidiostats and other medicinal substances with micro-organisms unless such a mixture is approved under the Community authorization authorising the micro-organism.

(4) Where a maximum or minimum content is specified in a Community authorization, the maximum or minimum content shall be construed so as to refer to complete feedingstuffs with a moisture content of 12 per cent, in so far as no special provisions are laid down in the said authorization.

(5) Where a substance which is permitted as an additive exists also in the natural state in certain ingredients of the feedingstuff, the amount of additive to be incorporated shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum content provided for in Community authorization.

8.The person responsible for putting an additive referred to in Part 1 of Annex C of the Council Directive into circulation must forward to the Commission of the European Communities, as soon as possible, the name or corporate name and the address or registered office of the producers to whom they have granted the right to manufacture the additive and, if the producers are established in a third country, also the name or corporate name and the address or registered office of their representatives in the Community.

9. (1) A person shall not market additives and premixtures other than in closed packages or closed containers.

(2) A package or container used for the purposes of paragraph (1) shall have a means of fastening the package or container which is so constructed that, if the means of fastening the package or container is damaged, the fastener is damaged on opening, it cannot be re-used.

10. (1) A person shall not manufacture, or put into circulation or feed to an animal, a supplementary feedingstuff for a species or category of animal which contains an additive in excess of the maximum level fixed for the corresponding complete feedingstuffs in the Commission regulation authorising use of the additive for that species or category of animal.

(2) Subject to paragraph 3 of this regulation, where a supplementary feedingstuff is such that were it mixed with other feedingstuffs prior to feeding, or fed as such in conjunction with other feedingstuffs, in accordance with instructions issued by its manufacturer and printed on, or on a label attached to, its packaging or, in case the supplementary feedingstuff is delivered in bulk, on documents accompanying the feedingstuff, the resulting feedingstuff or the daily ration as appropriate would comply with the requirements of paragraph (1), then the said requirement shall, as regards the supplementary feedingstuff, be regarded as having been complied with, provided that the supplementary feedingstuff has one or more characteristics (for example, a feed or mineral block or the content of crude protein or minerals) which in practice ensures that the level of additives fixed for a complete feedingstuff for that species or category of animal is not exceeded and that the feedingstuff is not used for other species or categories of animals.

(3)The provisions of paragraph 2 shall not apply to supplementary feedingstuffs containing antibiotics, coccidiostats or other medicinal substances or growth promoters in excess of five times the maximum level fixed for the corresponding complete feedingstuff which are put into circulation for use by persons not approved under Regulation 4 of the European Communities (Approval and Registration of Establishments or Intermediaries operating in the Animal Feed Sector) Regulations, 1999.

11. (1)A person shall not supply an additive listed in Part A of Annex A of the Directive unless the additive -

(a) has been manufactured by an approved establishment,

(b) has been supplied to an approved intermediary or establishment which manufactures premixtures, and

(c) is supplied in the form of a premixture to an approved intermediary or establishment which manufactures compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding.

(2) The provisions of this regulation shall apply without prejudice to Articles 4(2) and 9(2) of Council Directive 95/69/EC.

12. (1) person shall not supply an additive referred to in Part B of Annex A of the Directive unless:-

(a) the additive has been manufactured by an approved establishment,

(b) the additive has been supplied to an approved intermediary or establishment, and

(c) the additive is supplied in the form of a premixture to -

(i) an approved intermediary, or

(ii) an approved or registered establishment which manufactures compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding.

(2) The provisions of this regulation shall apply without prejudice to Articles 4(2) and 9(2) of Council Directive 95/69/EC.

13. (1) A person shall not incorporate an additive referred to in Part A or B of Annex A of the Directive in a compound feedingstuff unless-

(a) the additive has been prepared beforehand in the form of a premixture by an establishment which meets the conditions laid down in Article 2(2)(b) of Directive 95/69/EC,

(b) the rate of incorporation of the premixture in the compound feedingstuff is given in the directions for use on the label of the premixture and such rate is at least 0.2 per cent. by weight, and

(c) the premixture has been incorporated in the compound feedingstuff at the rate specified on the label.

(2) A person shall not have on any premises used for the manufacture of additives, premixtures or feedingstuffs an additive referred to in paragraph (1), or a premixture containing such an additive, unless -

(a) the premises is approved in accordance with Article 2(2)(b), (c) or (e)or Article 3(1) of Council Directive 95/69/EC to supply or use such additive or premixture, and

(b) the requirements of the said Articles are complied with.

(3) The provisions of this regulation shall apply without prejudice to Articles 4(2) and 9(2) of Council Directive 95/69/EC.

14. (1) Additives referred to in Part B of Annex A to the Council Directive may be supplied to approved intermediaries or registered establishments which manufacture compound feedingstuffs for pet animals and which fulfil the conditions laid down, as appropriate, in Article 3(1) or Article 7(2)(c) or (d) of Directive 95/69/EC.

(2) Additives referred to in Part A or B of Annex A to the Council Directive may be delivered at the last stage of circulation to establishments which manufacture compound feedingstuffs, provided that -

(a) direct addition to feedingstuffs is permitted in respect of a specific preparation of the additive in the Community authorization authorising the additive,

(b) the manufacturer of the compound feedingstuffs is approved in accordance with Article 2(2)(c) of Council Directive 95/69/EC for the additives referred to in Part A of Annex A of the Council Directive or is registered in accordance with Article 7(2)(c) of Council Directive 95/69/EC for the additives referred to in Part B of Annex A to the Council Directive, and

(c) an authorised officer has checked that the manufacturer is in possession of the appropriate technology defined in Chapter I (3)(b) or Chapter II (c) of the Annex to Council Directive 95/69/EC in order to add the preparation in question directly to the compound feedingstuff.

15. (1) A person shall not put authorised additives into circulation for use in feedingstuffs, unless the particulars, which must be clearly visible, readily legible and indelible -

(a) being

(i) in the case of all additives, with the exception of enzymes and micro-organisms, referred to in paragraph (2),

or

(ii) in the case of enzymes or micro-organisms, referred to in paragraph (4),

and

(b) referred to in paragraph (3),

are set out on the package or container in which the additives are packed or on a label attached thereto.

(2) The particulars referred to in subparagraph (1)(a)(i) to be displayed in respect of all additives, with the exception of enzymes and micro-organisms, shall be -

(a) the specific name given in the additive authorization, the EC registration number of the additive and, in the case of an additive within the meaning of Article 2 (aaa) of the Council Directive, the trade name and the registration number given to the person responsible for putting it in circulation;

(b) the name or business name and the address or registered place of business of the person responsible for the particulars specified in this paragraph;

(c) the net weight and, in the case of liquid additives, either the net volume or the net weight;

(d) as applicable and with effect from 1 April 2001, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of the said Directive .

(3) The particulars referred to in subparagraph (1)(b) shall be in respect of -

(a) antibiotics, growth promoters, coccidiostats and other medicinal substances:

(i) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label,
(ii) the active substance level,
(iii) the expiry date of the guarantee or storage life from the date of manufacture,
(iv) batch reference number,
(v) date of manufacture,
(vi) directions for use, and
(vii) where appropriate, a safety recommendation regarding use in the case of additives which are the subject of special provisions upon authorization;

(b) vitamin E:
(i) the alpha-tocopherol level,
(ii) the expiry date of the guarantee of that level or storage life from the date of manufacture;

(c) vitamins (other than vitamin E), provitamins and substances having a similar effect:
(i) the active substance level,
(ii) the expiry date of the guarantee of that level or storage life from the date of manufacture;

(d) trace elements, colorants including pigments, preservatives and other additives with the exception of those belonging to the enzyme and mirco-organism groups:
(i) the active substance level;

(4)The particulars referred to in paragraph (1)(a)(ii) to be displayed in respect of enzymes and micro-organisms, shall be in respect of -

(a) enzymes:

(i) the specific name of the active component or components in accordance with their enzymatic activities in conformity with the authorization given,
(ii) the identification number according to the International Union of Biochemistry,
(iii) the activity units, expressed as μmole of product released per minute per gram or per millilitre of enzymatic preparation,
(iv) the EC registration number of the additive,
(v) the name or business name and the address or registered place of business of the person responsible for the particulars on the label and the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label,

(vi) the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC with effect from 1 April 2001,
(vii) the expiry date of the guarantee or the storage life from the date of manufacture,
(viii) the batch reference number and the date of manufacture
(ix) the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage by weight of target feed material per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case- by-case basis in the authorization for the additive,
(x) where appropriate, safety recommendations as provided for in the authorization for the additive,
(xi) the net weight and, in the case of liquid additives, either the net volume or the net weight,
(xii) where appropriate indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization for the additive;

(b) micro-organisms:

(i) the identification of the strain in accordance with the authorization granted,
(ii) the file number of the strain,
(iii) the number of colony-forming units (CFU per gram),
(iv) the EC registration number of the additive,
(v) the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label,
(vi) the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC with effect from 1 April 2001,
(vii) the expiry date of the guarantee or the storage life from the date of manufacture,
(viii) the batch reference number and the date of manufacture
(ix) the directions for use,
(x) where appropriate, the safety recommendations as provided for in the authorization for the additive,
(xi) the net weight and, in the case of liquid additives, either the net volume or the net weight,
(xii) where applicable, an indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning the labelling in the authorization of the additive.

(5) The specific name of the additive may be accompanied in cases where the indications are not required by virtue of paragraph (1) by:

(i) the trade name,
(ii) the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label,
(iii) directions for use,
(iv) where appropriate, a safety recommendation regarding use.

(6) Information other than that specified in paragraphs (1), (2), (3), (4) and (5) may appear on packages, provided that it is clearly separated from the information required under the above mentioned paragraphs.

16. (1) A person shall only market premixtures if the following particulars, which shall be clearly visible, readily legible and indelible are given on the package, the container or a label affixed thereto:

(A) For all premixtures:

(i) the description "premixture";
(ii) directions for use, and any safety recommendations regarding the use of the premixture;
(iii) the animal species or category of animal for which the premixture is intended;
(iv) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;
(v) the net weight and, in the case of liquids, either the net volume or the net weight;
(vi) as applicable and with effect from 1 April 2001, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of that Directive.

(B) In addition for the premixtures incorporating the additives listed below:

(a) for antibiotics, growth promoters, coccidiostats and other medicinal substances:
(i) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the details on the label,
(ii) the specific name given to the additive upon authorization,
(iii) the active substance level,
(iv) the expiry date of the guarantee of that level or the storage life from the date of manufacture.

(b) for substances having antioxidant effects:
(i) the specific name given to the additive upon authorization
(ii) the active substance level: provided that a maximum level is fixed for complete feedingstuffs on authorization of the additive;

(c) for colorants, including pigments:
(i) the specific name given to the additive upon authorization
(ii) the active substance level: provided that a maximum level is fixed for complete feedingstuffs on authorization of the additive;

(d) for vitamin E
(i) the specific name given to the additive upon authorization;
(ii) the alpha-tocopherol level,
(iii) the expiry date of the guarantee of that level or the storage life from the date of manufacture;

(e) for vitamins (other than vitamin E), provitamins and substances having a similar effect:
(i) the specific name given to the additive upon authorization,
(ii) the active substance level,
(iii) the expiry date of the guarantee of that level or the storage life from the date of manufacture;

(f) for trace elements:
(i) the specific name given to the additive upon authorization,
(ii) the level of the various elements in so far as a maximum level is fixed for complete feedingstuffs upon authorization of the additive;

(g) for preserving agents:
(i) the specific name given to the additive upon authorization
(ii) the active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorization of the additive;

(h) for enzymes:
(i) the specific name of the active component or components according to their enzymatic activity in accordance with the authorization given,
(ii) the identification number according to the International Union of Biochemistry;
(iii) the activity units (activity units per kg or activity unit per ml);
(iv) the additive's EC registration number,
(v) the expiry date of the guarantee or the storage life from the date of manufacture,
(vi) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars of the label;
(vii) the batch reference number and the date of manufacture
(viii) the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage by weight of target feed material per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorization for the additive,
(ix) where applicable, an indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;

(i) for micro-organisms:
(i) the identification of the strains in accordance with the authorization given,
(ii) the file number of the strains;
(iii) the number of colony-forming units (CFU/g);
(iv) the additive's EC registration number
(v) the expiry date of the guarantee or the storage life from the date of manufacture,
(vi) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, and
(vii) the batch reference number and the date of manufacture
(viii) where applicable, an indication of the particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
(j) for other additives belonging to the groups referred to in (b) to (i) for which no maximum level is laid down and additives belonging to other groups authorised;

(i) the specific name given to the additive upon authorization;

(ii) the active substance level, provided that these additives fulfil a function in the feedingstuff as such and the amounts present can be determined by official methods of analysis or, failing this, by valid scientific methods.

(2) The following information may appear on packages:

(a) the specific name of the additives may be accompanied by the tradename,
(b) the name of the producer of the additives referred to paragraph 1(B)(a) may be indicated in the labelling of premixtures,
(c) the specific name of the additives authorised may be accompanied by the additives's EC registration number.

(3) Information other than that specified in paragraphs (1) and (2) may appear on the package, container or on the label affixed thereto, provided that it is clearly separated from the information required under the above mentioned paragraphs.

17. (1) A person shall not put feedingstuffs incorporating the additives belonging to the groups listed below into circulation unless the following particulars which must be clearly visible, readily legible and indelible are given on the package, container or a label affixed thereto.

(a) for antibiotics, coccidiostats and other medicinal substances and growth promoters:
(i) the specific name given to the additive upon authorization,
(ii) the active substance level
(iii) the expiry date of the guarantee of that level or storage life from the date of manufacture
(iv) the approval number assigned to the establishment in accordance with Article 5 of Directive 95/69/EC with effect from 1 April 2001.

(b) for substances having antioxidant effect:
(i) in the case of pet foods: use of the words "with antioxidant" followed by the specific name given to the additive upon authorization
(ii) in the case of compound feedingstuffs other than pets foods; the specific name given to the additive upon authorization;

(c) for colorants, including pigments provided that these are used for the coloration of feedingstuffs or animal products:
(i) in the case of pet foods: use of the words "colorant"or "coloured with" followed by the specific name given to the additive upon authorization
(ii) in the case of compound feedingstuffs other than pets foods; the specific name given to the additive upon authorization;

(d) for vitamin E:
(i) the specific name given to the additive upon authorization,
(ii) the alpha-tocopherol level
(iii) the expiry date of the guarantee of that level or storage life from the date of manufacture

(e) for vitamins A and D:
(i) the specific name given to the additive upon authorization,
(ii) the active substance level

(iii) the expiry date of the guarantee of that level or storage life from the date of manufacture;

(f) for copper:
(i) the specific name given to the additive upon authorization,
(ii) the level expressed in Cu;

(g) for preserving agents:
(i) in the case of pet foods: use of the words "preservation"or "preserved with" followed by the specific name given to the additive upon authorization
(ii) in the case of compound feedingstuffs other than pets foods; the specific name given to the additive upon authorization;

(h) for enzymes:
(i) the specific name of the active component or components according to their enzymatic activity in accordance with the authorization given,
(ii) the identification number according to the International Union of Biochemistry;
(iii) the activity units (activity units per kg or activity unit per litre);
(iv) the additive's EC registration number,
(v) the expiry date of the guarantee or the storage life from the date of manufacture,
(vi) where applicable, an indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;

(i) for micro-organisms:
(i) the identification of the strain(s) in accordance with the authorization given,
(ii) the number of colony-forming units (CFU/kg)
(iii) the file number of the strain(s)
(iv) the EC registration number of the additive
(v) the expiry date of the guarantee or the storage life from the date of manufacture
(vi) where applicable, an indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive.

(2) In addition to the particulars provided for in paragraph (1), the person responsible for the labelling particulars must ensure that any particulars concerning their proper use, which are laid down in the Community authorization for the additive, appear on the package or the container or on a label affixed thereto.

(3) The presence of trace elements other than copper and of vitamins other than vitamins A, D and E, provitamins and additives having a similar effect may be indicated if the amounts of these substances can be determined by official methods of analysis or failing this, by valid scientific methods of analysis. In such cases the following details shall be given:

(a) for trace elements other than copper:
(i) the specific name of the additive in accordance with the authorization given ,
(ii) the level of the various elements;

(b) for vitamins other than A, D and E, provitamins and substances having a similar chemical effect:

(i) the specific name of the additive in accordance with the authorization given,

(ii) the active substance level,

(iii) the expiry date of the guarantee of that level or the storage life from the date of manufacture;

(4) (a) The details specified to in paragraphs (1), (2) and (3) must be printed close to the particulars which have to appear on the package, container or the label affixed thereto in accordance with Community rules on feedingstuffs.

(b) Where a level or a quantity is stated pursuant to paragraphs (1) to (3), such statements shall refer to the amount of additive incorporated in the feedingstuff.

(c) The details of additives may be accompanied by the EC registration number of the additive or the trade name where those particulars are not required by virtue of paragraph (1).

18. Where, pursuant to Regulation 15, 16 or 17, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated or may be stated under of these Regulations, a single date of guarantee or a single reference to the storage life from the date of manufacture may be indicated for all the additives; provided, that the date mentioned shall be that which is the earliest of each of these dates.

19. (1) Where feedingstuffs are distributed by road tankers or similar vehicles or in bulk the details provided for in Regulation 17 shall be given in a document accompanying the feedingstuff.

(2) Where small quantities of feedingstuffs that are intended for the end-user are involved, it shall be sufficient for the details provided for in Regulation 18 of these Regulations to be conveyed to the purchaser by a special notice.

20. In the case of pet foods containing colorants, preservatives or substances having antioxidant effects and put in packages having a net weight of not more than 10 kilograms, it shall be sufficient that the particulars to be shown on a package bear the words “coloured with” or “preserved with” or “with antioxidant” as appropriate followed by the words “EC additives” provided that:

(a) the package, container or label bears a reference number by means of which the feedingstuff may be identified, and

(b) the manufacturer gives, on request, the specific name, or names of the additive or additives used.

21. A person shall not refer to additives on the packaging, labelling of or other documents in connection with additives, premixtures or feedingstuffs other than in the form provided for in these Regulations.

22. (1) Without prejudice to the provisions of Council Directive 79/373/EEC of 2 April 1979[35] and Regulation 10, a person shall not put into circulation supplementary feedingstuffs which contain additives in excess of the maximum level fixed for complete feedingstuffs unless the directions for use state, according to the species and age of the animal, the maximum quantity in grams or kilograms of supplementary feedingstuff to be given to each animal each day.

(2) The information referred to in paragraph (1) must be in accordance with the conditions of use prescribed upon authorization of the additive.

(3) This Regulation shall not apply to products delivered to manufacturers of compound feedingstuffs or to their suppliers.

(4) The directions for use referred to in paragraph (1) shall be so formulated that, when it is correctly followed, the proportion of additives does not exceed the maximum level fixed for complete feedingstuffs.

[35] O.J. No L 86, 6.4.79, p.30

23. A person shall not pack or export additives, premixtures or feedingstuffs for use in other Member States unless the details referred to in Regulations 15 to 22 of these Regulations are given in at least one of the official languages of the country of destination.

24. Every person who carries on, or is employed in connection with, the putting into circulation of additives, premixtures or feedingstuffs shall keep records or his or her transactions in such additives, premixtures or feedingstuffs.

Part III
Enforcement

Powers of Authorised Officers.

25. (1)The Minister may appoint in writing such and so many persons as the Minister thinks fit to be authorised officers for the purposes of all or any of the provisions of these Regulations and the Council Directive.

(2)Every authorised officer shall be furnished with a warrant of his or her appointment as an authorised officer stating that he or she is acting under these Regulations.

(3)An authorised officer, on production of the officer's authorization, if so required by any person affected, may, for the purposes of these Regulations and the Council Directive -

(a) subject to paragraph (5), at all reasonable times -

(i) enter and search any premises or place at which he or she has reasonably grounds for believing that there are additives, premixtures or feedingstuffs, or

(ii) board and search any railway wagon, vehicle, ship, vessel or aircraft in which he or she has reasonable grounds for believing that additives, premixtures or feedingstuffs are either being transported or kept for the purpose of transporting,

(b) there or at any other place, carry out such examinations, tests, or inspections as the officer reasonably considers necessary or expedient for the purposes of his or her functions under these Regulations and the Council Directive,

(c) take, without payment, such samples of any substance, at the premises or place or on the wagon, vehicle, ship, vessel or aircraft as he or she may reasonably require for the purposes of such functions and carry out or have carried out on the samples such examination checks and inspections to ensure that the requirements imposed by these Regulations are met,

(d) require any person at the premises or place or the owner or person in charge thereof and any person employed in connection therewith to give him such information and to produce to him or her such books, documents and other records within the power or procurement of the

person as he or she may reasonably require for the purposes of such functions,

(e) examine and take copies of, or extracts from, any such records (including in the case of information in non-legible form a copy of or extract from such information in permanent legible form), and give to the officer any information which he or she may reasonably require in relation to any entries therein;

(f) be afforded reasonable facilities for inspecting the stock of any additives, premixtures or feedingstuffs which is for the time being on any premises on which such person carried on such a business;

(g) seize or detain any product or thing to which these Regulations apply which he reasonably believes has been manufactured or imported or intended for use on the premises.

(4)An authorised officer, where the officer has reason to believe that any vehicle, railway wagon, vessel or aircraft has on board any additive, premixture or feedingstuff or thing the subject of these Regulations, may, on production of the officer's authorization, if so required by any person affected, if accompanied by a member of the Garda Síochána or an officer of Customs and Excise in uniform, stop the vehicle.

(5)An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless the officer has obtained a warrant from the District Court under paragraph (6) authorising such entry.

(6)If a judge of the District Court is satisfied by information on oath by an authorised officer that there is reasonable cause for suspecting that -

(a) evidence of or relating to the commission or intended commission of an offence under these Regulations is to be found in any premises or place,

(b) there is or was any product or thing the subject of these Regulations in any premises or place, or

(c) a document directly or indirectly connected with any product or thing the subject of these Regulations is in the possession or control of a person in any premises or place,

such judge may issue a warrant authorising a named authorised officer, accompanied by such authorised officers, members of the Garda Síochána or officers of Customs and Excise as the named officer thinks necessary, at any time or times within one month from the date of issue of the warrant, on production if so requested of the warrant, to enter (if necessary by force) the premises or place named in the warrant.

(7)Where a premises or place is entered under a search warrant issued under paragraph (6) all or any of the powers set out in paragraph (3) may be exercised by the authorised officer who so enters.

(8)A person who obstructs or otherwise interferes with an authorised officer in the performance of the officer's functions under these Regulations or who, in purported compliance with a requirement under paragraph (3)(d), gives information to an authorised officer that he or she knows to be false or misleading in a material respect shall be guilty of an offence.

26. (1) Where a person has on his or her premises any additive, premixture or feedingstuff which he or she has purchased and which he or she proposes to use in the course of his farming operations, he or she may apply to the Minister to have a sample thereof taken for analysis.

(2) An application under this Regulation shall be -

(a) made within the period of 60 days beginning on the date on which the additive, premixture or feedingstuff to which the application relates was delivered to the applicant, and

(b) accompanied by such fee as determined by the Minister.

(3) Where an application is made under this Regulation, an authorised officer shall, subject to paragraph (4) -

(a) take and deal with a sample of the relevant additive, premixture or feedingstuff according to the methods described in the Annex to Commission Directive 76/371/EEC[36], and

(b) give or cause to be given, or send by registered post or by such other method as for the time being stands approved of for the purposes of this paragraph by the Minister, to the State Chemist and to the person whose name or trade name appears on the label of the additive, premixture or feedingstuff or, in the case of an imported additive, premixture or feedingstuff, the importer, samples prepared pursuant to the requirements of subparagraph (a).

(4) Where an application is made under this Regulation, an authorised officer may, if he or she thinks fit, decline to take a sample if -

(a) he or she is not satisfied that the applicant has purchased the additive, premixture or feedingstuff to which the application relates,

(b) he or she is not satisfied that the applicant proposes to use the additive, premixture or feedingstuff in the course of his farming operations,

(c) he or she is not satisfied that the additive, premixture or feedingstuff as presented for sampling is fairly representative of the additive, premixture or feedingstuff as delivered to the applicant, or

(d) the applicant does not furnish such information relating to such additive, premixture or feedingstuff as the authorised officer may reasonably require.

(5) Where the State Chemist receives a sample taken in pursuance of the application under this Regulation, he or she shall, in making an analysis thereof, comply with such official methods of analysis as apply in the particular case and send to the applicant and to the person (other than the State Chemist) refereed to in paragraph (3)(b) a certificate, in the form set out in the European Communities (Feedingstuffs) (Methods of Sampling and Analysis)Regulations, 1999 (S.I. No 289 of 1999), of the result of the analysis.

[36] O.J. No L 102, 15.4.76, p.1

(6) Subject to paragraph (8), all fees under this Regulation shall be paid into or disposed of for the benefit of the Exchequer in accordance with the directions of the Minister for Finance.

(7) Nothing in this Regulation shall be construed as requiring the State Chemist to make a test, examination or analysis regarding the presence in or absence from a sample given or sent to him or her pursuant to these Regulations of any particular substance, product or other thing, if in his opinion there is not in relation to such presence or absence a method of testing, examination or analysis which is sufficiently reliable or if there is not available to the State Chemist the apparatus or other means by which such a test, examination or analysis could be made.

(8) In any case in which he or she considers it proper so to do (not being a case in which the applicant has received a certificate under this Regulation), the Minister may refund a fee paid in relation to an application under this Regulation.

(9) For the purposes of this Regulation a feedingstuff shall not be regarded as having been delivered to a purchaser until it arrives at the destination to which it is assigned whether the consignment is by direction of the supplier or the purchaser.

27. A person who, with intent to deceive-

(a) tampers with any product or thing the subject of these Regulations so that a sample of it taken, does not accurately represent the aforementioned product or thing or,

(b) tampers or interferes with any sample under these Regulation,

shall be guilty of an offence.

28. Where an authorised officer is satisfied that an additive, premixture or feedingstuff which is placed on the market, or which he believes will be placed on the market, does not comply with any one or more of the requirements of these Regulations, he or she may require either or both of the following persons, namely, the person who appears to him to have, for the time being, possession or control of the additive, premixture or feedingstuff, and the person whose name or trade name appears on the label of the additive, premixture or feedingstuff to take such steps as are necessary to ensure that it does not continue to be placed on the market, or, as may be appropriate, is not placed on the market until such authorised officer is satisfied that the requirement is complied with.

29. (1)Where a sample of an additive, premixture or feedingstuff is taken pursuant to these Regulations by an authorised officer and is found on official examination not to comply with a requirement of these Regulations, the Minister may require that the additive, premixture or feedingstuff shall be destroyed or otherwise disposed of in such manner as the Minister shall determine.

(2)In case the Minister makes a requirement under this Regulation the following provisions shall apply :

(a) he or she shall inform in writing of the requirement the person who is in possession or control of the additive, premixture or feedingstuff to which the requirement relates;

(b) where a notice is given, a person shall not, without the consent of the authorised officer by whom the notice was directed, move, dispose of interfere with or otherwise deal with the product or thing the subject of these Regulations other than in compliance with the requirements of the notice; and

(c) the person in such possession or control shall dispose of the additive, premixture or feedingstuff or cause or permit it to be disposed of, only in accordance with the requirement.

(3) Any person who is aggrieved by a notice under this Regulation may, not later than 21 days after the date of the notice, or any further period (if any) as the District Court may allow, appeal against the notice to the District Court.

(4) Notice of an appeal under paragraph (3) shall be given to the Minister by the person bringing the appeal at least 7 days prior to the hearing of the appeal.

(5) (a) Where an appeal is brought under paragraph (3), the District Court shall make such order as it considers just (including an

order directing that the product or thing the subject of these Regulation be disposed of, at the expense of the owner, in such manner as it may specify).

(b) the cost of disposal by an authorised officer under this Regulation or pursuant to an order of the District Court under this Regulation shall be recoverable by the Minister by whom it is incurred as a simple contract debt in any court of competent jurisdiction from the person who was the owner of the product or thing the subject of these Regulations at the time of its seizure and detention under these Regulations.

30.Where a sample of an additive, premixture or feedingstuff is taken pursuant to these Regulations by an authorised officer, a person shall not move the additive, premixture or feedingstuff, as the case may be, during the period of seven working days immediately following the day on which the sample is taken, without the consent of an authorised officer and, where a consent under this Regulation is given, a person shall not move the additive, premixture or feedingstuff concerned other than in accordance with the terms and conditions of the consent.

31. (1) An authorised officer who takes a sample under Regulation 25, or a sample in respect of which an application for sampling under Regulation 26 has been made, shall -

(a) in respect of such sample, comply with the Annex to Commission Directive 76/371/EEC of 1 March 1976[36] , establishing Community methods of sampling for the official control of feedingstuffs, and

(b) forward a final sample thereof (within the meaning of the said Annex) to -

(i) the State Chemist, and

(ii) the person who put the additive, premixture or feedingstuffs into circulation.

(2) As soon as practicable after he or she has received a final sample forwarded under paragraph (1) the State Chemist shall carry out an analysis of the sample and determine its composition.

32. In any proceedings the production of a certificate in the form specified in these Regulations and purporting to be signed by the State Chemist shall, without proof of any signature on the certificate or that the signatory was the proper person to sign it, be sufficient evidence of the facts stated in the certificate and of the analysis to which it relates having been carried out in accordance with such of the requirement (if any) specified in the official methods of analysis as applied in the particular case.

33. (1) The Minister may direct an authorised officer, from time to time, to take random samples of additives, premixture and feedingstuffs to establish the identity of additives and to verify that the conditions laid down in these Regulations are satisfied.

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[36] O.J. No L 102, 15.4.76, p.1

(2) A person intending to manufacture additives (other than medicinal additives) or place them on the market shall inform the Minister of his intention in writing to manufacture additives or place additives on the market.

34. Where an unforeseen undesirable interaction between additives referred to in Article 2 aaa of the Council Directive and other additives or veterinary medicines occurs, the person responsible for putting the additive into circulation or his representative within the Community where the additive originates in a third country, shall be required to gather all relevant information and forward it to the Minister.

35. (1) A person who -

(a) contravenes Part II of these Regulations or Regulation 30

(b) obstructs or interferes with an authorised officer in the course of exercising a power conferred on him by Regulation 25,

(c) fails to comply with a requirement of an authorised officer pursuant to Regulation 28, or with a requirement of the Minister pursuant to Regulation 29,

shall be guilty of an offence.

(2) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,500.

(3) An offence under these Regulations may be prosecuted by the Minister.

(4)Where an offence is committed under these Regulations by a body corporate and is proved to have been so committed with the consent, connivance or approval of or to have been attributable to the wilful neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate or a person who was purporting to act in any such capacity, that person, as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against and punished as if he or she was guilty of the first-mentioned offence.

36. The following Regulations are hereby revoked:

(a) the European Communities (Additives in Feedingstuffs) Regulations, 1989 (S.I. No. 49 of 1989),

(b) the European Communities (Additives in Feedingstuffs) (Amendment) Regulations, 1995 (S.I. No. 9 of 1995),

(c) the European Communities (Marketing of Enzymes, Microorganisms and their Preparations in Animal Nutrition) Regulations, 1995 (S.I. No 237 of 1995),

(d) the European Communities (Additives in Feedingstuffs) (Amendment) Regulations, 1997 (S.I. No. 127 of 1997), and

(e) the European Communities (Additives in Feedingstuffs) (Amendment) Regulations, 1998 (S.I. No. 205 of 1998).

(f) the European Communities (Marketing of Enzymes, Microorganisms and their Preparations in Animal Nutrition) (Amendment) Regulations, 1998 (S.I. No 169 of 1998)

GIVEN under my Official Seal,
this 2nd day of December, 1999.

L.S.

Joe Walsh

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Minister for Agriculture, Food.
and Rural Development.

Explanatory Note

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Regulations, deal with the putting into circulation and the use of additives and premixtures in feedingstuffs, consolidate existing legislation and implement additional amendments made to Council Directive 70/524/EEC. The Regulations revoke the European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1998.

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